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10/532,391	04/21/2005	Norman Booth	559022001200	1816

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EXAMINER	
HELLING, KAITLYN ELIZABETH	
ART UNIT	PAPER NUMBER
3739	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,391	BOOTH ET AL.	
	Examiner	Art Unit	
	KAITLYN E. HELLING	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed on April 07, 2009 has been entered. Claims 1-24 remain pending in the application, claims 25-27 have been cancelled and claim 28 is newly added.

Response to Arguments

2. Applicant's arguments with respect to claims 1 and 13 have been considered but are moot in view of the new ground(s) of rejection.

3. Applicant's arguments filed April 07, 2009 have been fully considered but they are not persuasive.

With respect to applicant's argument that it would not make sense to one of skill to use a ferrite core in view of the Glasband disclosure, the examiner respectfully disagrees. Applicant points to the fact that Glasband is operable at common power and thus would not require a ferrite core transformer. However, as the transformer of Glasband is being combined with the multi-phase radio-frequency ablation device of Desai, the device of Glasband will be operating at radio-frequency energies. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Glasband to have included a ferrite core as ferrite is a known ferromagnetic material with a high initial permeability and is commonly used in radio frequency transformer devices.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 28 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of the ground reference of the tap and indifferent electrode connected to a ground reference on the primary side of the transformer is not described in the specification or referenced in the drawings. In fact, the indifferent or reference electrode is only described as being connected to the center tap 24 of the secondary winding of transformer 12.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-9, 13-22 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 5,892,667 to Glasband et al. (Glasband) in view of U.S. 5,620,481 to Desai et al. (Desai).

Regarding claim 1, Glasband teaches a symmetrical power system with a transformer (12, Fig. 1 and Abstract) having a primary (14, Fig. 1 and Col. 5, lines 47-48) and secondary winding (16 and 18, Fig. 1 and Col. 5, line 48-50), the secondary winding having a center tap (20, Fig. 1) which is connected to ground (30, Fig. 1 and Col. 5, lines 56-57), two sources for supplying energy (Fig. 1) and the energy output at the ends of the two sources being out of phase with on another (Col. 5, lines 65-66).

Glasband, however, does not teach the use of a ferrite core, radio frequency energy, an active electrode connected to the energy sources to apply energy to the site of application. Desai teaches a device for multi-phase radio-frequency ablation (title) which includes a two-dimensional or three-dimensional electrode array (Abstract).

The circuit of Glasband is particularly suited to be implemented with the ablation device of Desai as Glasband teaches that the symmetrical power supply is uniquely configured and referenced to operate sensitive electronics, i.e. electrodes, and other impedance loads, i.e. the body, in a manner that inhibits propagation of most interference. The circuit of Glasband further provides for the energy to be cut in half but retain the total energy output as desired by the applicant for ablation. Therefore, it would have been obvious to have one having ordinary skill in the art at the time of the invention to have used the circuit of Glasband for the above stated reasons with the radio frequency energy source and the attached electrodes of Desai as Desai teaches that the use of multi-phase radio frequency with an electrode array produces a multitude of current paths on the surface of the ablation zone as well as results in a uniform lesion (Abstract).

Regarding the use of a ferrite core, as ferrite is a known ferromagnetic material with a high initial permeability and is commonly used in radio frequency device, it would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the core of Glasband with a ferrite core, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Regarding claim 2, Glasband and Desai teach the system of claim 1 with Glasband teaching the primary winding being connected to an output of an energy generator (Fig. 1). However, Glasband does not teach the energy generator supplying radio frequency energy. Desai teaches the further limitation of the inclusion of a radio frequency energy generator (220, Fig. 2a and Col. 6, lines 61-62). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Glasband and Desai to have included the further limitation of the energy generator producing radio frequency energy as Desai teaches that radio frequency ablation is advantageous since it does not require anesthesia and produces more circumscribed and discrete lesions and avoids injury caused by high voltages (Col. 2, lines 30-34).

Regarding claim 3, Glasband and Desai teach the system of claim 1, with Desai teaching the connection of a reference electrode (Col. 7, lines 24-36). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Glasband and Desai to have further included the reference electrode of Desai as Desai teaches that by connecting one or more of the electrodes in the array to the ground terminal it will eliminate the need for a backplate and thus allow for various permutations of the current paths to form on the tissue's surface (Col. 7, lines 24-36).

Regarding claim 4, Glasband and Desai teach the system of claim 1, with Glasband teaching that any desired voltage can be achieved by the appropriate selection of the ratio of output to input turns of a transformer (Col. 6, lines 29-31). The examiner asserts that it would, therefore, have been obvious to one having ordinary skill

in the art at the time of the invention to have used a transformer with a 1:1 ratio between the primary and secondary windings if that ratio provided the desired outcome (See MPEP 2144.05).

Regarding claim 5, Glasband and Desai teach the system of claim 1 with Glasband teaching the further limitation of the center tap providing two sub-windings (16 and 18, Fig. 1) which act as energy sources (Col. 5, lines 60-64) with the energy supplied being 180° out of phase with respect to each other (Col. 5, lines 65-66).

Regarding claims 6 and 7, Glasband and Desai teach the system of claim 5 with Desai teaching the further limitation of the electrodes attached to the free end of each sub-winding with the electrodes arranged in groups relative to the site being treated (Fig. 8 and Col. 9, lines 41-50). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Glasband and Desai to have included the further limitation of the electrodes attached to the sub-windings and arranged in groups relative to the site being treated of Desai since Desai teaches that this is the preferred electrode array and that by the judicious pairing of the electrodes, a two-phase radio frequency supply is able to produce a fairly uniform lesion (Col. 9, lines 12-21).

Regarding claim 8, Glasband and Desai teach the system of claim 6, with Desai teaching to provide more than two connections to the radio frequency energy generator (Fig. 2a and Col. 6, lines 48-62). Therefore, the examiner asserts that it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Glasband and Desai to have included intermediate taps between the ground

reference tap and the free end of each sub-winding to provide more than two sub-windings acting as energy sources since the mere duplication of parts has no patentable significance unless a new and unexpected result is produced (See MPEP 2144.04).

Regarding claim 9, Glasband and Desai teach the system of claim 1, with Desai teaching the electrode assembly comprising a co-axially arranged pair of electrodes which are displaceably arranged relative to each other (Figs. 8a, 8b and Col. 9, line 41 – Col. 10, line 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to have further modified Glasband and Desai to have included the further limitation of a co-axially arranged pair of electrodes because Desai teaches that this is a preferred embodiment since the pair of the electrodes a two-phase radio frequency energy supply is able to produce a fairly uniform lesion (Col. 9, lines12-16).

Regarding claim 13, Glasband teaches a symmetrical power system providing a transformer (12, Fig. 1 and Abstract) having a primary (14, Fig. 1 and Col. 5, lines 47-48) and secondary winding (16 and 18, Fig. 1 and Col. 5, line 48-50), the secondary winding having a center tap (20, Fig. 1) which is connected to ground (30, Fig. 1 and Col. 5, lines 56-57), two sources for supplying energy (Fig. 1) and the energy output at the ends of the two sources being out of phase with on another (Col. 5, lines 65-66). Glasband, however, does not teach the use of radio frequency energy or connecting an active electrode to the energy sources to apply energy to the site of application. Desai teaches a device for multi-phase radio-frequency ablation (title) which has a two-dimensional or three-dimensional electrode array connected to a radio frequency

energy generator (Abstract). It would have been obvious to have modified Glasband to have included the radio frequency energy source and the connected electrodes of Desai as teaches that the use of multi-phase radio frequency with an electrode array produces a multitude of current paths on the surface of the ablation zone as well as results in a uniform lesion (Abstract).

Regarding claim 14, Glasband and Desai teach the method of claim 13 with Glasband teaching the primary winding being connected to an output of an energy generator (Fig. 1). However, Glasband does not teach the energy generator supplying radio frequency energy. Desai teaches the further limitation of the inclusion of a radio frequency energy generator (220, Fig. 2a and Col. 6, lines 61-62). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Glasband and Desai to have included the further limitation of the energy generator producing radio frequency energy as Desai teaches that radio frequency ablation is advantageous since it does not require anesthesia and produces more circumscribed and discrete lesions and avoids injury caused by high voltages (Col. 2, lines 30-34).

Regarding claim 15, Glasband and Desai teach the method of claim 13, with Desai teaching the connection of a reference electrode (Col. 7, lines 24-36). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Glasband and Desai to have further included the reference electrode of Desai as Desai teaches that by connecting one or more of the electrodes in the array to

the ground terminal it will eliminate the need for a backplate and thus allow for various permutations of the current paths to form on the tissue's surface (Col. 7, lines 24-36).

Regarding claim 16, Glasband and Desai teach the method of claim 13, with Glasband teaching that the selection of a desired voltage can be achieved by the appropriate selection of the ratio of output to input turns of a transformer (Col. 6, lines 29-31). The examiner asserts that it would, therefore, have been obvious to one having ordinary skill in the art at the time of the invention to have used a transformer with a 1:1 ratio between the primary and secondary windings if that ratio provided the desired outcome (See MPEP 2144.05).

Regarding claim 17, Glasband and Desai teach the method of claim 13 with Glasband teaching the further limitation of the center tapping the transformer to provide two sub-windings (16 and 18, Fig. 1) which act as energy sources (Col. 5, lines 60-64) with the energy supplied being 180^{o} out of phase with respect to each other (Col. 5, lines 65-66).

Regarding claims 18 and 19, Glasband and Desai teach the method of claim 17 with Desai teaching the further limitation of connecting the electrodes to the free end of each sub-winding with the electrodes arranged in groups relative to the site being treated (Fig. 8 and Col. 9, lines 41-50). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Glasband and Desai to have included the further limitation of the electrodes being connected to the sub-windings and arranged in groups relative to the site being treated of Desai since Desai teaches that this is the preferred electrode array and that by the judicious pairing of the

electrodes, a two-phase radio frequency supply is able to produce a fairly uniform lesion (Col. 9, lines 12-21).

Regarding claim 20, Glasband and Desai teach the method of claim 18, with Desai teaching to form more than two connections to the radio frequency energy generator (Fig. 2a and Col. 6, lines 48-62). Therefore, the examiner asserts that it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Glasband and Desai to have included intermediate taps between the ground reference tap and the free end of each sub-winding to provide more than two sub-windings acting as energy sources since the mere duplication of parts has no patentable significance unless a new and unexpected results is produced (See MPEP 2144.04).

Regarding claim 21, Glasband and Desai teach the method of claim 18, with Desai teach the further limitation of the electrode being placed transmurally at a site (Col. 1, line 60 – Col. 2, line 10). It would have been obvious to have modified Glasband and Desai to have included the further limitation of the electrode being placed transmurally as taught by Desai for treating cardiac dysrhythmias (Col. 1, line 16 - Col. 2, line 10).

Regarding claim 22, Glasband and Desai teach the method of claim 18, with Desai teaching arranging of the electrode assembly as a co-axially arranged pair of electrodes which are displaceably arranged relative to each other (Figs. 8a, 8b and Col. 9, line 41 – Col. 10, line 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to have further modified Glasband and Desai to have

included the further limitation of a co-axially arranged pair of electrodes because Desai teaches that this is a preferred embodiment since the pair of the electrodes a two-phase radio frequency energy supply is able to produce a fairly uniform lesion (Col. 9, lines12-16).

Regarding claim 28, Glasband teaches a symmetrical power system with a transformer (12, Fig. 1 and Abstract) having a primary (14, Fig. 1 and Col. 5, lines 47-48) and secondary winding (16 and 18, Fig. 1 and Col. 5, line 48-50), the secondary winding having a center tap (20, Fig. 1) which is connected to ground (30, Fig. 1 and Col. 5, lines 56-57), two sources for supplying energy (Fig. 1) and the energy output at the ends of the two sources being out of phase with on another (Col. 5, lines 65-66). Glasband, however, does not teach the use of a ferrite core, radio frequency energy, an active electrode connected to the energy sources to apply energy to the site of application. Desai teaches a device for multi-phase radio-frequency ablation (title) which includes a two-dimensional or three-dimensional electrode array (Abstract).

The circuit of Glasband is particularly suited to be implemented with the ablation device of Desai as Glasband teaches that the symmetrical power supply is uniquely configured and referenced to operate sensitive electronics, i.e. electrodes, and other impedance loads, i.e. the body, in a manner that inhibits propagation of most interference. The circuit of Glasband further provides for the energy to be cut in half but retain the total energy output as desired by the applicant for ablation. Therefore, it would have been obvious to have one having ordinary skill in the art at the time of the invention to have used the circuit of Glasband for the above stated reasons with the

radio frequency energy source and the attached electrodes of Desai as Desai teaches that the use of multi-phase radio frequency with an electrode array produces a multitude of current paths on the surface of the ablation zone as well as results in a uniform lesion (Abstract).

Regarding the use of a ferrite core, as ferrite is a known ferromagnetic material with a high initial permeability and is commonly used in radio frequency device, it would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the core of Glasband with a ferrite core, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Desai also teaches the connection of a reference electrode to a ground terminal (Col. 7, lines 24-36) which will necessarily be the ground reference of the tap. It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Glasband and Desai to have further included the reference electrode of Desai as Desai teaches that by connecting one or more of the electrodes in the array to the ground terminal it will eliminate the need for a backplate and thus allow for various permutations of the current paths to form on the tissue's surface (Col. 7, lines 24-36). In light of the lack of any disclosed criticality for the specific arrangement of the connection of the ground reference to the tap and the indifferent electrode being connected to a ground reference on the primary side of the transformer, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified

Glasband and Desai as it has been held that the mere rearrangement of parts is not patentably significant if it does not impact the operation of the device.

8. Claims 10-12 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 5,892,667 to Glasband et al. and U.S. 5,620,481 to Desai et al. as applied to claims 9 and 22 above, and further in view of U.S. 6,497,704 B2 to Ein-Gal (Ein-Gal).

Regarding claim 10, Glasband and Desai teach the system of claim 9, but not at least one of the electrodes having a helical tip. Ein-Gal teaches an electrosurgical apparatus (title) which includes an electrode with a helical tip for screwing the electrode into the site (Col. 5, lines 48-53 and Col. 6, lines 12-17). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Glasband and Desai with the helical tip of Ein-Gal as Ein-Gal teaches that it is preferable to be able to screw the electrode into a tissue (Col. 6, lines 12-17).

Regarding claim 11, Glasband, Desai and Ein-Gal teach the system of claim 10, with Ein-Gal teaching the further limitation of both electrodes of the assembly being helically tipped to be screwed into the site (Figs. 6A, 6B and Col. 10, lines 18-40). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Glasband, Desai and Ein-Gal to have included the further limitation of both electrodes being helically tipped as Ein-Gal teaches that it is advantageous to be able to screw the electrode into a tissue (Col. 6, lines 12-17).

Regarding claim 12, Glasband, Desai and Ein-Gal teach the system of claim 11, with Ein-Gal teaching the further limitation of the helical-tipped electrodes being of

different pitches (Col. 6, lines 18-22). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Glasband, Desai and Ein-Gal with the further limitation of the helical-tipped electrodes being of different pitches since Ein-Gal teaches that the longitudinal direction of the lesion is basically dependent on the length of the electrode that is inserted into the tissue (Col. 1, lines 29-42).

Regarding claim 23, Glasband and Desai teach the method of claim 22, but not providing that at least one of the electrodes having a helical tip. Ein-Gal teaches an electrosurgical apparatus (title) which includes an electrode with a helical tip for screwing the electrode into the site (Col. 5, lines 48-53 and Col. 6, lines 12-17). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Glasband and Desai with the helical tip of Ein-Gal as Ein-Gal teaches that it is preferable to be able to screw the electrode into a tissue (Col. 6, lines 12-17).

Regarding claim 24, Glasband, Desai and Ein-Gal teach the method of claim 23, with Ein-Gal teaching the further limitation of both electrodes of the assembly being helically tipped to be screwed into the site (Figs. 6A, 6B and Col. 10, lines 18-40) and the helical-tipped electrodes being of different pitches (Col. 6, lines 18-22). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Glasband, Desai and Ein-Gal to have included the further limitation of both electrodes being helically tipped and of different pitches as Ein-Gal teaches that it is advantageous to be able to screw the electrode into a tissue (Col. 6, lines 12-17) and

that the longitudinal direction of the lesion is basically dependent on the length of the electrode that is inserted into the tissue (Col. 1, lines 29-42).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAITLYN E. HELLING whose telephone number is (571)270-5845. The examiner can normally be reached on Monday - Friday 9:00 a.m. to 5:30 p.m. EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571)272-4764. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KAITLYN E. HELLING/
Examiner, Art Unit 3739

/Roy D. Gibson/
Primary Examiner, Art Unit 3739